Attachment A
Summary of Safety and Effectiveness

Prepared in accordance with 21 CFR Part 807.92(c).

Date Prepared 25-May-2005

Establishment Name and Registration Number

Manufacturer Name and Address:	GVI Medical Devices 1470 Enterprise Parkway Twinsburg, Ohio 44087
Contact:	Kevin Murrock
Telephone:	330-963-4083, x113
Fax:	330-963-4084
E-mail:	kevin.murrock@gvitp.com
Registration Number:	3003917438

Device Name and Classification

21 CFR Number:	892.1100
CDRH Product Code:	90 IYX
Regulatory Device Class:	I
Classification Panel:	Radiology
Proprietary Name:	OnePass Nuclear Medicine Imaging System
Common Name:	Gamma Camera System
Classification Name:	Camera, Scintillation (Gamma)

Reason for 510(k) Submission

Modification

Predicate Device

OnePass Nuclear Medicine Imaging System, 510(k) Number: K023373

Device Description

The OnePass Nuclear Medicine Imaging System acquires and processes gated First Pass Radionuclide Angiography (FPRNA) images. After completion of acquisition, both qualitative and quantitative results are available for processing and analysis.

The device consists of a vertical support, a single small FOV detector mounted on an articulating arm, a 15 in. color LCD acquisition display, and an acquisition and processing computer workstation. The OnePass system's small field-of-view (FOV) detector and small system footprint are designed for placement in a facility lacking adequate floor space for a typical nuclear medicine imaging system.

Intended Use

The OnePass nuclear medicine imaging system is intended for use as a diagnostic imaging device. Used with appropriate radiopharmaceuticals, it produces images that depict the anatomical distribution of radioisotopes within the human body. The OnePass system's compact footprint and small FOV detector are specifically designed for placement in a facility lacking adequate floor space for a typical nuclear medicine imaging system.

The OnePass system's design is optimized for acquiring and processing cardiac first pass data. First-pass radionuclide angiography (FPRNA) is used to assess left and right ventricular function at rest or during stress.

Substantial Equivalence

The modified OnePass is of a comparable type and substantially equivalent to the OnePass System (510(k) Number K023373). Both devices are used to perform First-Pass Radionuclide Angiography (FPRNA) studies and contain similar performance characteristics. This modification provides a slightly larger UFOV to aid the operator in ensuring the myocardium remains positioned within the detector UFOV throughout an entire stress acquisition. This modification also includes a new software application to automatically archive system-specific data files (e.g. calibration, user settings) to a remote Web-based storage system. This application does not archive patient data, only system data files. It has the same technological characteristics, is identical in key safety and effectiveness features, uses the same basic design, and has the same intended use as the predicate device.

Conclusion

The modified OnePass system does not result in any new potential safety risks and performs as well as the OnePass Nuclear Medicine Imaging System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 13 2005

Mr. Kevin M. Murrock
Manager, Quality and Regulatory
GVI Technology Partners
GVI Medical Devices
1470 Enterprise Parkway
TWINSBURG OH 44087

Re: K051402
Trade/Device Name: OnePass Nuclear Medicine Imaging System
Regulation Number: 21 CFR 892.1100
Regulation Name: Scintillation (gamma) Camera
Regulatory Class: I
Product Code: IYX
Dated: May 26, 2005
Received: May 31, 2005

Dear Mr. Murrock:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Attachment D
Indications for Use Statement

510(k) Number (if known): K051402

Device Name: OnePass Nuclear Medicine Imaging System

Indications for Use: The OnePass nuclear medicine imaging system is intended for use as a diagnostic imaging device. Used with appropriate radiopharmaceuticals, it produces images that depict the anatomical distribution of radioisotopes within the human body. The OnePass system's compact footprint and small FOV detector are specifically designed for placement in a facility lacking adequate floor space for a typical nuclear medicine imaging system.

The OnePass system's design is optimized for acquiring and processing cardiac first pass data. First-pass radionuclide angiography (FPRNA) is used to assess left and right ventricular function at rest or during stress.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801-109)

David A. Lyerson

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K051402